UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

KPH HEALTHCARE SERVICES, INC., a/k/a KINNEY DRUGS, INC., individually and on behalf of all others similarly situated, Plaintiff, v. ABBVIE INC.; ALLERGAN, INC.; ALLERGAN SALES, LLC; ALLERGAN USA, INC.; FOREST LABORATORIES, INC.; FOREST LABORATORIES HOLDINGS, LTD.; FOREST LABORATORIES, LLC; and FOREST LABORATORIES IRELAND, LTD., Defendants.	Case No. 1:20-cv-08754 **CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

I. INTRODUCTION

1. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. ("Plaintiff" or "KPH") brings this Class Action Complaint on behalf of itself and a putative Class of Direct Purchasers ("Class Members") of Bystolic® (nebivolol hydrochloride or nebivolol HCl) ("Bystolic") during the period from July 9, 2016 until the anticompetitive effects of Defendants' conduct cease (the "Class Period").

2. Defendants are AbbVie, Inc. ("AbbVie"); Allergan, Inc.; Allergan Sales, LLC; and Allergan USA, Inc. (collectively, "Allergan"); and Forest Laboratories, Inc.; Forest Laboratories Holdings, Ltd.; Forest Laboratories, LLC; and Forest Laboratories Ireland, Ltd. (collectively, "Forest"). AbbVie, Allergan and Forest are referred to together herein as "Defendants."

3. Plaintiff alleges that Defendants engaged in an unlawful conspiracy to monopolize the Bystolic market in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2.

4. As a result of Defendants' anticompetitive conduct, Plaintiff and members of a putative Direct Purchaser Class ("Class Members") sustained damages by paying more for Bystolic than they otherwise would have paid in the absence of Defendants' unlawful conduct.

5. Accordingly, Plaintiff, on behalf of itself and other Class Members, seeks redress for overcharge damages sustained as a result of Defendants' antitrust violations. But for Defendants' illegal conduct, Plaintiff and Class Members would not have paid supra-competitive prices for Bystolic.

6. Plaintiff makes the allegations herein based on personal knowledge and the investigation of counsel, and upon information and belief as to all other matters.

II. NATURE OF THE CASE

7. Bystolic is a "beta blocker" drug prescribed to treat high blood pressure (hypertension). According to the Mayo Clinic, "[b]eta blockers, also known as beta-adrenergic blocking agents, are medications that reduce . . . blood pressure. Beta blockers work by blocking the effects of the hormone epinephrine, also known as adrenaline."[1]

8. Forest and its successors market and sell brand Bystolic in the United States. Forest's annual sales of Bystolic total nearly $1 billion.[2]

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[1] *See* https://www.mayoclinic.org/diseases-conditions/high-blood-pressure/in-depth/beta-blockers/art-20044522 (last visited September 13, 2020).

[2] Glenmark Pharmaceuticals received ANDA approval for Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg. *See* https://www.glenmarkpharma.com/sites/default/files/Glenmark-receives-ANDAapproval-for-Nebivolol-Tablets%2C2.5-mg%2C5-mg%2C10-mg-and-20-mg.pdf, May 29, 2017 (last visited September 13, 2020).

9. On or about December 17, 2011, generic drug manufacturers filed Abbreviated New Drug Applications ("ANDA") with the United States Food and Drug Administration ("FDA") to market generic Bystolic.

10. Generic competition would have drastically reduced revenue generated by Bystolic sales.

11. Generic prescription drugs perform the same as their branded counterparts, but typically cost 50% less. This generally allows generic prescription drugs to capture 80% or more of the market within the first nine months after they enter the market.

12. Generics also challenge the monopoly power and profits of branded manufacturers because drug substitution laws permit dispensing pharmacies to exchange branded drugs for bioequivalent generic drugs. This drastically reduces sales for brand manufacturers by millions of dollars.

13. To prevent generic competition for Bystolic, Forest orchestrated a series of unlawful reverse-payment agreements (also known as "pay for delay" deals) with potential generic competitors, specifically, Hetero Labs Ltd. and Hetero USA Inc. (collectively, "Hetero"); Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively, "Torrent"); Alkem Laboratories Ltd. ("Alkem"); Indchemie Health Specialties Private Ltd. ("Indchemie"); Glenmark Generics Inc., USA; Glenmark Generics Ltd.; and Glenmark Pharmaceuticals Ltd. (collectively, "Glenmark"); Amerigen Pharmaceuticals Ltd. and Amerigen Pharmaceuticals Inc. (collectively, "Amerigen); and Watson Pharma, Inc. and Watson Pharmaceuticals Inc. (collectively, "Watson"). These are collectively referenced herein as the "Generic Competitors."

14. On or about December 17, 2011, Forest sued the Generic Competitors for allegedly infringing U.S. Patent No. 6,545,040 (the '040 Patent") after the Generic Competitors became the

first companies to seek approval to market generic Bystolic. These suits automatically triggered stays of FDA approval of generic Bystolic

15. While the stays were in effect, the Generic Competitors fought the patent infringement suits. They also continued to prepare to bring their generic Bystolic to market, and at least six of the seven Generic Competitors obtained final FDA approval to do so, as follows:

Generic Manufacturer	ANDA No.	Final Date of Approval
Amerigen	203659	4-16-15
Alkem	203741	6-24-15
Indchemie	203828	7-29-15
Watson	203683	11-27-15
Glenmark	203821	5-25-17
Torrent	203966	3-2-18

16. In the interim, from October 2012 through November 2013, Forest made serial deals with each Generic Competitor to refrain from entering the market or competing with Forest with generic Bystolic before September 17, 2021, unless another generic manufacturer entered the market earlier. In exchange, Generic Competitors received "side deals" and cash payments.

17. These deals effectively foreclosed all manufacturers from bringing generic Bystolic to market because once one manufacturer files for generic approval, that manufacturer remains eligible for market exclusivity until 180 days after its generic product is launched. Consequently, once the Generic Competitors agreed to keep their generic Bystolic off the market until at least September 17, 2021, they effectively prevented any other generic Bystolic from entering the market until at least mid-March 2022.[3]

[3] The only exception would have been if Forest had approved an "authorized generic."

18. As corporate successors-in-interest to one or more of the Forest Defendants, Allergan, and then AbbVie, have continued this illegal collusion and unreasonable restraint of trade in the Bystolic market at the expense of purchasers.

19. Due to the '040 Patent's infirmities, the Generic Competitors would have prevailed in the patent litigation, which would have resulted in a launch by the later of: (a) June 2015, which was the expiry of the only other patent that Forest contended covered Bystolic (U.S. Patent No. 5,759,580, or the "'580 Patent"), or (b) the dates their ANDAs were finally approved, which, as shown above, started as early as April 2015.

20. Evidence of Forest's agreements with the Generic Competitors is found in materials relating to the equity and cash merger between Forest and Actavis PLC that was announced on February 18, 2014.[4]

21. On March 1, 2014 Forest's outside lawyers at Weil, Gotshal & Manges LLP were reviewing Forest's documents as part of their "work on the Actavis merger agreement."[5]

22. On March 4, 2014, Forest's outside lawyers informed Forest's in-house counsel, Eric Agovino, via email (the "Agovino email") that "before we engage in any discussions with the FTC . . . we think it would be prudent for us to review all of the Bystolic settlement and licensing agreements as well as the side agreements with those generic companies."[6] Agovino replied:

> "We entered into settlement agreements with the following defendants:
>
> 1) Hetero

[4] *See* Actavis to Acquire Forest Laboratories, Inc. for ~$25 Billion in an Equity and Cash Transaction, at https://www.buinesswire.com/news/home/20140218005877/en/Actavis-Acquire-Forest-Laboratories-25-Billion-Equity (last visited September 13, 2020).

[5] *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-cv-07488 (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-44 at 332).

[6] *Id.*

2) Torrent
3) Alkem
4) Indchemie
5) Glenmark
6) Amerigen
7) Actavis [Watson's successor]

All had side deals (one was struck with Alkem, which is a related company with Indchemie)."[7]

23. Forest's Merger Agreement with Actavis PLC from weeks earlier, dated February 17, 2014, provides additional details. Specifically, in the Merger Agreement, Forest disclosed its "material contracts," which are defined to include: "any Contract involving the settlement of any action or threatened action (or series of related actions) (A) which will (x) involve payments after the date hereof of consideration in excess of $15,000,000 or (y) impose monitoring or reporting obligations to any other Person outside the ordinary course of business or (B) with respect to which material conditions precedent to the settlement have not been satisfied."[8]

24. Each of the side deals with Generic Competitors listed below was designated by Forest as a "material contract" "in connection with the settlement of BYSTOLIC patent dispute," as follows:

a. **Hetero**: "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Hetero USA Inc. and Hetero Labs Ltd. dated October 24, 2012 . . . together with the FINAL TERM SHEET between Hetero Drugs Ltd. and Forest Laboratories Ireland Ltd. dated October 5, 2012, in connection with the settlement of BYSTOLIC patent dispute."[9]

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[7] *Id*.

[8] *In re Namenda Direct Purchaser Antitrust Litig*., 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 69).

[9] *Id* at 179.

b. **Torrent**: "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. dated November 21, 2012 . . . together with the PATENT ASSIGNMENT AGREEMENT between Torrent Pharmaceuticals Ltd and Forest Laboratories Holdings Ltd. dated November 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[10]

c. **Alkem/Indchemie**: "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem Laboratories Ltd. dated November 27, 2012 . . . together with the TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute. AMENDMENT NO. 1 TO SETTLEMENT AGREEMENT was executed on January 9, 2013" and "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Indchemie Health Specialties Private Ltd. dated November 27, 2012 . . . together with the TERM SHEET between Alkem Laboratories Ltd, Indchemie Health Specialties Private Ltd, and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute."[11]

d. **Glenmark**: "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Glenmark Generics Inc., USA

[10] *Id*.

[11] *Id*.

and Glenmark Generics Ltd. dated December 21, 2012 . . . together with the COLLABORATION AND OPTION AGREEMENT between Glenmark Pharmaceuticals S.A. and Forest Laboratories Holdings Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[12]

e. **Amerigen**: "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013 . . . together with the BINDING TERM SHEET COLLABORATION AGREEMENT between Forest Laboratories, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013, in connection with the settlement of BYSTOLIC patent dispute."[13]

f. **Watson**: "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Actavis, Inc. dated November 6, 2013 . . . together with (a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between Actavis, Inc. and Moksha8, Inc. dated November 4, 2013, in connection with the settlement of BYSTOLIC patent dispute."[14]

[12] *Id*.

[13] *Id* at 180.

[14] *Id*.

25. Forest listed the side deals in the Merger Agreement because, on information and belief, they "involve payments after the date [t]hereof of consideration in excess of $15,000,000."

26. Forest also "agreed to reimburse certain of the Settling Defendants' legal costs in connection with the patent litigation."[15]

27. Forest disclosed that its settlement agreements with the Generic Competitors "provide[d] a license to each of the Settling Defendants that will permit them to launch their respective generic versions of Bystolic as of the date that is the later of (a) three calendar months prior to the expiration of the '040 patent, including any extensions and/or pediatric exclusivities or (b) the date that each Settling Defendant receives final FDA approval of its ANDA, or earlier in certain circumstances."[16] The language "or earlier in certain circumstances" is known as a "contingent launch provision" ("CLP"), or an "acceleration clause." CLPs ensure a settling generic that it will not be competitively disadvantaged should a later-settling generic negotiate an earlier licensed entry date or otherwise come to market earlier. The CLPs allow that an entry date may be "accelerated" permitting the settling generic to enter the market at the same time as any of its competitors.

28. Under a CLP, the first-filing ANDA filer obtains protection from other first filers by agreeing to delay the launch of their generic products from the date of settlement until a date certain if all other first-filer generics follow suit. The date certain in this case is exactly three months before the expiration of the '040 Patent, or September 17, 2021.[17]

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[15] *See* https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm (last visited September 13, 2020).

[16] *Id*.

[17] *Id*.

29. Defendants' scheme has been successful. No competitor has or will enter the market until September 17, 2021.[18]

30. As alleged in more detail below, Defendants' scheme violated Sections 1 and 2 of the Sherman Act and caused injuries to Plaintiff and Class Members in the form of overcharges.

III. PARTIES

31. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. ("KPH") is a corporation organized under the laws of the State of New York, with headquarters in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. KPH is the assignee of McKesson Corporation, which directly purchased branded Bystolic during the Class Period and resold it to KPH. As a result of Defendants' alleged anticompetitive conduct, Plaintiff[19] paid supra-competitive prices for its Bystolic purchases and was injured by the illegal conduct alleged herein.

32. Defendant Forest Laboratories, Inc. is a corporation organized under the laws of Delaware. Its principal place business is located at 909 Third Avenue, New York, New York 10022. Forest Laboratories, Inc. became the limited liability company Forest Laboratories, LLC on July 14, 2014.

33. Defendant Forest Laboratories, LLC is organized and exists under the laws of Delaware. Its principal place is at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

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[18] *See, e.g.*, 11/27/2015 Letter from Food and Drug Administration ("FDA") to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf (last visited September 13, 2020).

[19] All references in this Complaint to damages sustained by Plaintiff relate to damages sustained by McKesson Corporation, for which the right to seek redress and recover damages has been assigned to Plaintiff.

34. Defendant Forest Laboratories Ireland, Ltd. is an Irish Corporation and its place of business was located at Clonshaugh Industrial Estate, Dublin 17, Ireland. In or around February 2006, Defendant Forest Laboratories Ireland, Ltd. became Forest Laboratories Holdings, Ltd. and changed its principal place of business to Bermuda.[20]

35. Defendant Forest Laboratories Holdings, Ltd. is a Bermudian corporation and its principal place of business is at 18 Parliament Street, Hamilton HM 11, Bermuda.

36. Defendant Forest Laboratories, Inc. was acquired by Actavis PLC ("Actavis") on July 1, 2014. Later, on May 17, 2015, Actavis also acquired Defendant Allergan, Inc. On, January 1, 2018, Forest Laboratories, LLC was merged with and into the Delaware limited liability company Allergan Sales, LLC.

37. Defendant Allergan Sales, LLC is a company organized and existing under the laws of Delaware, with its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

38. Defendant Allergan, Inc. is a Delaware corporation with its principal place of business located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

39. Defendant Allergan USA, Inc. is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

40. Allergan, through its merger with Forest, assumed responsibility for performance of the challenged provisions in the agreements, continued to perform those provisions, and

[20] *See, e.g.*, Notice and Stipulation of Name Change, *Forest Labs. v. Ivax Pharms., Inc.,* No. 03-cv-00891 (D. Del. Feb. 8, 2006) (ECF No. 536).

benefited from making direct sales of Bystolic to Plaintiff and Class Members at supra-competitive prices made possible by the delay those challenged provisions produced.[21]

41. On information and belief, Forest assigned the pay-for-delay deals to Allergan, and Allergan never withdrew from them.

42. On information and belief, Allergan joined the ongoing unlawful course of conduct – and joined the unlawful reverse-payment agreements – with respect to the suppression of generic competition for Bystolic. Allergan did not withdraw from those conspiracies and, instead, continued to participate in them.

43. Defendant AbbVie, Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is the corporate successor to Allergan and Forest, having completed its purchase of Allergan on May 8, 2020.

44. AbbVie, through its merger with Allergan, assumed responsibility for performance of the challenged provisions in the agreements, continued to perform those provisions, and benefited from making direct sales of Bystolic to Plaintiff and Class Members at supra-competitive prices made possible by the delay those challenged provisions produced.

45. On information and belief, Allergan assigned the pay-for-delay deals to AbbVie, and AbbVie never withdrew from them.

46. On information and belief, AbbVie joined the ongoing unlawful course of conduct – and joined the unlawful reverse-payment agreements – with respect to the suppression of generic

[21] *See, e.g.*, Bystolic label, listing Allergan USA Inc. as the distributor for Bystolic, at https://www.dailymed.nlm.nih.gov/dailymed/fdaDrugXsl.cfm?setid=8b8ad213-1dc8-454e-a524-075685c0e1a8&type=display (last visited September 13, 2020).

competition for Bystolic. AbbVie did not withdraw from those conspiracies and, instead, continued to participate in them.

47. Although not named as a Defendant, Hetero Labs Ltd. was an initiator of, and is a participant in, the unlawful conspiracy described in this Complaint. Hetero Labs Ltd. is an Indian corporation, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estate, Sanathnagar Hyderbad 500018 Andhra Pradesh, India.

48. Although not named as a Defendant, Hetero USA Inc. was an initiator of, and is a participant in, the unlawful conspiracy described in this Complaint. Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854. On information and belief, Hetero USA Inc. is a wholly-owned subsidiary, and acts as the agent, of Hetero Labs Ltd.

49. Although not named as a Defendant, Torrent Pharmaceuticals Ltd. was an initiator of, and is a participant in, the unlawful conspiracy described in this Complaint. Torrent Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Off. Ashram Road, Ahmedabad -380 009, Gujarat, India.

50. Although not named as a Defendant, Torrent Pharma Inc. was an initiator of. and is a participant in, the unlawful conspiracy described in this Complaint. Torrent Pharma Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 5380 Holiday Terrace, Suite 40, Kalamazoo, MI 49009. On information and belief, Torrent Pharma Inc. is a wholly-owned subsidiary, and acts as the agent, of Torrent Pharmaceuticals Ltd.

51. Although not named as a Defendant, Alkem Laboratories Ltd. was an initiator of, and is a participant in, the unlawful conspiracy described in this Complaint. Alkem Laboratories

Ltd. is an Indian company, having a place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (West), Mumbai 400013, Maharashtra, India.

52. Although not named as a Defendant, Indchemie Health Specialties Private Ltd. was an initiator of, and is a participant in, the unlawful conspiracy described in this Complaint. Indchemie Health Specialties Private Ltd. is an Indian company, having a place of business at 510, Shah & Nahar Industrila Estate, Dr. E. Moses Road, Worli-Mumbai 400018, India.

53. Although not named as a Defendant, Glenmark Generics Inc., USA was an initiator of, and is a participant in, the unlawful conspiracy described in this Complaint. Glenmark Generics Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, NJ 07430. Glenmark Generics Inc. is the same entity as Glenmark Generics Inc., USA. To the extent Glenmark Generics Inc. is an entity separate and apart from Glenmark Generics Inc., USA, any allegations in this Complaint relating to Glenmark Generics Inc., USA shall apply equally to Glenmark Generics Inc.

54. Although not named as a Defendant, Glenmark Generics Ltd. was an initiator of, and is a participant in, the unlawful conspiracy described in this Complaint. Glenmark Generics Ltd. is an Indian company, having a place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India. On information and belief, Glenmark Generics Inc., USA is the North American division of Glenmark Generics Ltd.

55. Although not named as a Defendant, Defendant Glenmark Pharmaceuticals Ltd. was an initiator of, and is a participant in, the unlawful conspiracy described in this Complaint. Glenmark Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western

Express Highway, Mumbai 400099, Maharashtra, India. On information and belief Glenmark Generics Inc., USA and Glenmark Generics Ltd. are wholly-owned subsidiaries of Glenmark Pharmaceuticals Ltd.

56. On information and belief, Glenmark Generics Inc., USA; Glenmark Generics Ltd.; and Glenmark Pharmaceuticals Ltd. have officers and directors in common. On information and belief, Glenmark Generics Inc., USA acts as the agent of Glenmark Generics Ltd. and Glenmark Pharmaceuticals Ltd.

57. Although not named as a Defendant, Amerigen Pharmaceuticals Ltd. was an initiator of, and is a participant in, the unlawful conspiracy described in this Complaint. Amerigen Pharmaceuticals Ltd. is a Chinese company, having places of business at 197 State Route 18S, Suite 306N, East Brunswick, NJ 08816 and No. 58, Qunxing Yi Road, Suzhou Industrial Park, PRC. 215006.

58. Although not named as a Defendant, Amerigen Pharmaceuticals Inc. was an initiator of, and is a participant in, the unlawful conspiracy described in this Complaint. Amerigen Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 197 State Route 18S, Suite 306N, East Brunswick, NJ 08816. On information and belief, Amerigen Pharmaceuticals Inc. is a wholly-owned subsidiary, and acts as the agent, of Amerigen Pharmaceuticals Ltd.

59. Although not named as a Defendant, Watson Pharma, Inc. was an initiator of, and is a participant in, the unlawful conspiracy described in this Complaint. Watson Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

60. Although not named as a Defendant, Watson Pharmaceuticals, Inc. was an initiator of, and is a participant in, the unlawful conspiracy described in this Complaint. Watson Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Nevada, having places of business at 311 Bonnie Circle, Corona, CA 92880 and 360 Mount Kemble Avenue, Morristown, NJ 07962, and its corporate headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

61. All of the actions of Defendants and their unnamed (as defendants) co-conspirators' described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' and their unnamed co-conspirators' officers, agents, employees, or other representatives while actively engaged in the management of the affairs of Defendants and their unnamed co-conspirators (or of their predecessors-in-interest), within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants and their unnamed co-conspirators.

IV. JURISDICTION AND VENUE

62. This action arises under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover treble damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by Plaintiff and members of the Class (defined below) resulting from Defendants' conspiracy and scheme to restrain trade in the market for Bystolic in the United States. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1407; and 15 U.S.C. §§ 15, 22.

63. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a) and 22, and 28 U.S.C. §§ 1391(b), (c), and (d), because during the class period, Defendants resided, transacted business, were found, and/or had agents in the United States and in this District, and a substantial portion of

the alleged conduct that affected interstate trade and commerce discussed herein has been carried out in the United States and in this District.

64. Defendants' conduct, as described in this Complaint, was within the flow of, and was intended to and did have a substantial effect on, the interstate commerce of the United States, including in this District.

65. During the class period, Forest manufactured, sold, and shipped Bystolic in a continuous and uninterrupted flow of interstate commerce, and their anticompetitive conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

66. During the class period, each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their scheme.

67. This Court has personal jurisdiction over each Defendant because each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal scheme and conspiracy throughout the United States, including in this District. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

68. This Court has personal jurisdiction over each Defendant under 15 U.S.C. § 22 because each transacts business in this District.

69. Personal jurisdiction lies under Fed. R. Civ. P. 4(k)(2) over the foreign domiciliary Defendants.

70. This Court has specific personal jurisdiction under CPLR § 302(a) over all Defendants because Forest, from its then-principal place of business in New York, NY, did all of the following: (a) entered into the agreements containing the challenged reverse payments to each

Defendant; (b) made the promised reverse payments to each Defendant; (c) enforced each Defendant's agreement to delay entry of its generic Bystolic in consideration for those reverse payments; (d) sold branded Bystolic at supracompetitive prices made possible by the generic delay those reverse payments to each Defendant purchased; and (e) earned as a result of those sales ill-gotten gains from the delay in generic Bystolic competition that those reverse payments to each Defendant purchased. Moreover, on information and belief, some or all of the agreements containing the challenged reverse payments direct application of New York law and select a New York forum.

V. LEGAL AND REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand-name Drugs.

71. Manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA") under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

72. When the FDA accepts a brand manufacturer's NDA, the manufacturer may list in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (also known as the "Orange Book") patents related to the drug compound, formulations, and methods of use that the manufacturer thinks could reasonably be asserted against a generic manufacturer that seeks approval for a generic version of the brand drug prior to the expiration of the listed patents. The manufacturer may list in the Orange Book, within thirty (30) days of issuance, any patents issued after the FDA approved the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

73. The FDA's act of listing a submitted patent in the Orange Book is purely ministerial. The FDA relies completely on the brand manufacturer's truthfulness about patent

validity and applicability, as it does not have the time to verify the manufacturer's patents for accuracy or trustworthiness.

B. The Hatch-Waxman Amendments Advance the Public Policy of Providing Access to Lower Cost Generic Pharmaceuticals.

74. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need to file lengthy and costly NDAs for compounds that had already been approved by the FDA.[22] Following passage of the Hatch-Waxman Act, a generic manufacturer seeking approval to sell a generic version of a brand-name drug was permitted to file an ANDA.

75. An ANDA relies on the scientific findings of safety and effectiveness included in the brand-name drug manufacturer's original NDA. For an oral dosage form, the generic drug must show that it performs equivalently to brand name drug, i.e. that the generic has the same active ingredient(s), dosage form, route of administration, strength, and achieves the same blood levels of drug in the same time frame as the brand-name drug. When a generic product meets these requirements, the FDA assigns the oral generic drug an "AB" rating.[23] meaning that the generic drugs is bioequivalent to the brand-name drug.

76. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients in the

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[22] *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[23] Generic manufacturers can also seek approval of non-AB-rated generics. The FDCA permits "hybrid" applications that are neither full NDAs containing safety and efficacy data, nor ANDA applications showing that the proposed product is the "same" as the NDA product. 21 U.S.C. § 505(b)(2). Drug products approved under this section use a safe and effective active pharmaceutical ingredient, but modify the drug product in some way so that it differs from the original NDA product, either in dosage form, strength, route of administration, formulation, dosing regimen, or indication. These non-AB-rated generics are not bioequivalent to the innovator product. *See* 21 C.F.R. § 314.54.

same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Thus, bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart.[24]

77. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of generic drugs, thereby reducing healthcare expenses nationwide while balancing pharmaceutical companies' incentives to create new and innovative products.

78. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches and ushering in an era of historic high profit margins for brand-name pharmaceutical companies. In 1983, pre-Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic versions available; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generics totaled $21.6 billion and generic drugs accounted for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion and generic drugs accounted for 75% of prescriptions.

C. ANDA Patent Certifications Provide Incentives to Generic Manufacturers to Challenge Patents.

79. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

a) that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

b) that the patent for the brand drug has expired (a "Paragraph II certification");

[24] 21 U.S.C. § 355(j) (8) (B).

c) that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

d) that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

80. If a generic manufacturer files a Paragraph IV certification, it must notify the brand manufacturer, and the brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for alleged patent infringement. Should the brand manufacturer initiate a patent infringement action against the generic filer within forty-five (45) days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months from the date of receipt of the Paragraph IV notice, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). The FDA may grant "tentative approval," meaning that all regulatory issues are resolved, but cannot authorize the generic manufacturer to go to market as the patents block the granting of final approval.

D. The First-Filer has a 180-Day Exclusivity Period.

81. Generics may be classified as (i) first-filer generics, (ii) later generic filers, and (iii) an authorized generic.

82. To motivate manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA with a Paragraph IV certification a 180-day period to exclusively market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug. 21 U.S.C. §§ 355(j)(5)(B)(iv), 355(j)(5)(D).

83. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first filer.[25]

84. A first-filer generic that informs the FDA that it intends to wait until all Orange Book listed patents expire before marketing its product does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents, or to invent around such patents by creating non-infringing generics.

85. Where (as here) multiple generic companies are the first to file substantially complete ANDAs with Paragraph IV certifications, each is considered a "first applicant" and may be eligible to share the 180-day exclusivity period.[26] If at least one first applicant remains eligible for the exclusivity, *i.e.*, if the exclusivity has not been extinguished or forfeited, all subsequent ANDA filers must wait until the 180-day period expires before they can launch.

E. Launches of AB-Rated Generics Creates Competition.

86. Since the FDA deems AB-rated generic versions of brand drugs to be just as safe and effective as their brand counterparts, the only material mode of differentiating the two drugs is their price. On average, generics are at least 50% - 80% less expensive when there are multiple generic competitors on the market for a given brand.

87. Every state has adopted laws that either require or permit pharmacies to automatically substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has affirmatively requested the brand). Accordingly, once one generic equivalent enters the market, the generic quickly captures sales of the corresponding brand drug, often 80% or more within the first six months.

[25] *FTC v. Actavis, Inc.*, 570 U.S. 136, 144 (2013).

[26] 21 U.S.C. § 355(j)(5)(B)(iv).

88. The Federal Trade Commission ("FTC") has found that, on average, by 12 months post-generic entry, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85% relative to brand prices.[27] That is because once multiple generic competitors enter, the competitive process typically accelerates by multiple generic sellers competing vigorously with each other for market share by driving prices further down toward marginal manufacturing costs.[28] As a result, competition from generic drugs is viewed by brand drug companies, such as Forest, as a grave financial threat.

89. Generic competition enables purchasers (like Class Members here) to purchase substantially less expensive generic versions of a drug instead of the more expensive brand, and to purchase generic versions of a drug at increasingly lower prices as more generic versions of that brand drug enter the market, causing generic prices to fall further.[29] In addition, generic competition enables purchasers to pay lower prices for their remaining brand purchases when the brand company lowers its brand price to compete with the generic for sales.

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[27] *See* FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 8 (Jan. 2010), at http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf ("FTC Pay-for-Delay Study") (last visited September 13, 2020).

[28] *See*, *e.g.*, Patricia Danzon & Li-Wei Chao, Does Regulation Drive Out Competition in Pharmaceutical Markets?, 43 J.L. & ECON. 311, 314, 339-41, 354-55 (Oct. 2000); Tracy Regan, Generic Entry and Price Competition in the Prescription Drug Market--18 Years after the WaxmanHatch Act 24-25 (Univ. of Miami, Dep't of Econ., Working Paper, Feb. 14, 2004); Richard G. Frank, The Ongoing Regulation of Generic Drugs, 357 NEW ENG. J. MED. 1993, 1993-96 (Nov. 2007).

[29] *See*, *e.g.*, Ernst R. Berndt & Murray L. Aitken, Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation 19-20 (Nat'l Bureau of Econ. Research, Working Paper No. 16431, Oct. 2010); CONGRESSIONAL BUDGET OFFICE, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry, at 32-33 (Jul. 1997); David Reiffen & Michael R. Ward, Generic Drug Industry Dynamics, 87 REV. OF ECON. AND STAT., 37, 43-44 (2005).

90. Conduct that delays generic entry harms direct purchasers (like Plaintiff and Class Members here) in several ways. One way that direct purchasers are harmed is that they are forced to continue purchasing the more expensive brand drug instead of the lower-priced generic equivalent they would have purchased had the generics entered earlier. In addition, conduct that delays generic entry causes direct purchasers to pay inflated generic prices because (a) generic prices fall over time, and so generic prices would have been lower if generic competition had started earlier and (b) because the generic price is discounted off the brand price,[30] and because brand prices typically increase over time,[31] the generic prices would have been lower if the generics had launched earlier, when the brand price was lower.

91. Once exclusivity is lost and generic entry occurs – an event sometimes referred to as the "patent cliff" – the brand manufacturer can expect a significant drop in profits, as it is forced to either compete by dramatically lowering prices or accept dramatically lower sales.

92. The tradeoff (of longer exclusivity rights in return for quick and effective generic entry after loss of exclusivity) was fundamental to the policies and procedures that Congress established in the Hatch-Waxman Act and states embraced in their generic substitution laws.

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[30] In order to be automatically substituted for the corresponding brand, generic products must be less expensive than the corresponding brand. *E.g.*, Cal. Bus. & Prof. Code § 4073(c); Tx. Admin. Code § 309.3(a)(1); Fla. Stat. § 465.025(2); 35 Pa. Code § 960.3(a); N.Y. Educ. Law § 6816-a. Generic prices are set as a percentage discount off the brand price. *See*, *e.g.*, *In re Namenda Antitrust Litig.*, No. 15-cv-07488 (S.D.N.Y. Mar. 5, 2019) (ECF No. 668-4) (assumption listed in cell A43 of a pharmaceutical manufacturer sales forecast is that the generic will initially be priced at a 40% discount off the brand price and then will drop to a 90% discount from the brand price).

[31] The price of brand Bystolic has increased substantially over the last five years. For example, Defendants increased the price of the 10 mg tablet of Bystolic repeatedly and significantly over the last five years, by 8.5% in October 2015, 9% in April 2016, 9% in January 2017, 9.5% in January 2018, 9.5% in January 2019, and 5% in January 2020 – in total increasing the price of the 10 mg tablet of Bystolic by 62% over the last five years. Defendants imposed nearly identical price increases on the other strengths of Bystolic, increasing the prices of the various strengths of Bystolic by 60-62% over the period from June 2015 through today.

93. The FDA affirmed the cost savings of generic drugs, "According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics."[32]

F. Brand and Generic Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms.

94. Because the Hatch-Waxman regulatory scheme automatically delays approval of an ANDA whenever a brand-name manufacturer sues the potential generic competitor for alleged patent infringement, brand-name manufacturers frequently take aggressive positions in listing patents in the Orange Book, and then bring patent lawsuits against any generic competitor that files an ANDA with a Paragraph IV certification. Brand-name manufacturers often sue generics simply to delay generic competition, rather than to enforce valid patents against infringing products.

95. In connection with the resolution of patent litigation arising out of Paragraph IV Certifications, some brand-name manufacturers have entered into "settlements" in which the brand-name manufacturer pays off its generic competitors in exchange for a delay in generic competition. These exclusion-payment non-compete agreements among horizontal competitors are commonly known as "pay-for-delay" or "reverse-payment" agreements, because these settlements are contrary to the traditional patent settlement framework where a patent holder obtains royalty payment from an infringer. These purported patent litigation settlements preserve the brand manufacture's monopoly and increased profits intact by a payment of some of the monopoly profits to the generic manufacturer that, in turn, agrees to delay marketing its product.

[32] *Generic Drugs Undergo Rigorous FDA Scrutiny*, U.S. Food & Drug Admin. (Oct. 8, 2014), https://www.fda.gov/consumers/consumer-updates/generic-drugs-undergo-rigorous-fda-scrutiny (last visited September 13, 2020).

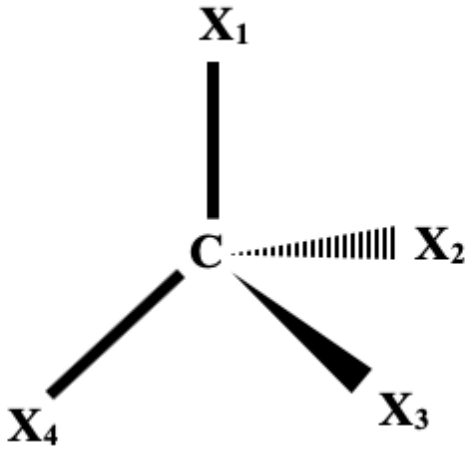
96. Initially, reverse-payment agreements took the form of a straight cash payment from the brand-name manufacturer to the generic competitor. As a result of regulatory scrutiny, congressional investigations, and class action lawsuits, brand-name manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive character of their agreements.

VI. FACTUAL ALLEGATIONS

A. Basic Chemistry Relating to the Active Pharmaceutical Ingredient in Bystolic.

97. Molecules are composed of atoms (*e.g.*, carbon, nitrogen, or hydrogen) that are bonded to each other through the sharing of electrons. The atom carbon forms four bonds, the arrangement of which can be envisioned as a tetrahedron with the carbon atom at the center and the four substituents at the four vertices of the tetrahedron.

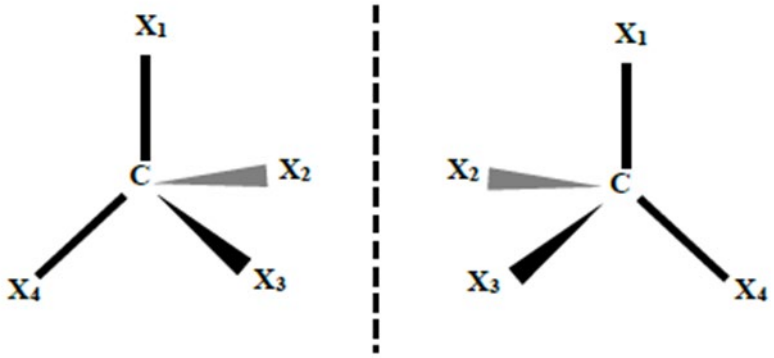
98. The chemical symbol for the carbon atom is "C." The figure below shows a carbon atom (labeled as "C") bonded to four different chemical substituents (labeled as "X1," "X2," "X3," and "X4").



The straight lines from the carbon atom (at the center) to "X1" and "X4" are intended to convey that they are in the plane of the page. The solid wedge from the carbon atom to "X3" is intended

to demonstrate that it is coming out of the page towards the reader. Lastly, the hashed wedge from the carbon atom to "X2" is intended to convey that it is coming out of the page but away from the reader. Thus, the above figure reflects a three-dimensional tetrahedral structure with a carbon atom at its center.

99. When a carbon atom is attached to four different substituents in a tetrahedral arrangement such as that depicted above, the substituents can be arranged in either of two conformations, as demonstrated below, with a mirror line between them.



Note that, much like one's left and right hands, they are mirror images of each other; however, they cannot be superimposed on one another by rotation. A carbon atom bonded to four different substituents can thus exist as either of two "stereoisomers" and such a carbon atom is referred to as a "chiral center." Naming conventions exist to differentiate these two stereoisomers from one another, and a commonly used terminology refers to one configuration as the "R" configuration and the other as the "S" configuration.

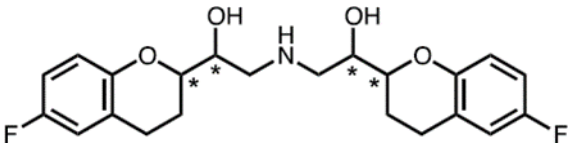
100. Distinguishing between stereoisomers can be particularly important in biological systems because many active pharmaceutical ingredients ("APIs") in drugs interact with naturally occurring receptors in the human body by fitting into a three-dimensional site on the receptor, similar to a left hand fitting into a left-handed glove. Just as a left hand would not fit properly into a right-handed glove, the wrong stereoisomer often will not fit into the intended receptor site.

Therefore, it is not uncommon for one stereoisomer to exhibit a desired pharmacological activity in biological systems while the other does not.

101. Carbon is so ubiquitous in organic chemicals that a carbon atom in chemical structures is often abbreviated as a vertex, rather than as a "C," with the understanding that such vertices are carbon.

102. The chemical symbol for hydrogen is "H." Hydrogen forms only one bond. Since hydrogen also is ubiquitous and the number of chemical bonds that carbon and hydrogen make (i.e., 4 and 1, respectively) is so well known, hydrogen is often omitted from chemical structures and its presence is assumed when a carbon has less than four bonded substituents.

103. Mixtures of stereoisomers were disclosed in a prior art patent, United States Patent No. 4,654,362 ("the '362 Patent"). On March 31, 1987, the United States Patent and Trademark Office ("PTO") issued the '362 Patent, which disclosed a number of different chemical compounds, including the following chemical compound:



104. The unlabeled vertices above correspond to a carbon atom and each of those carbon atoms (vertices) is connected to other atoms. To the extent a specific carbon atom has less than four bonds depicted, the remainder are hydrogen atoms. With this understanding in mind, each asterisk in the above chemical structure corresponds to a chiral center – i.e., a carbon atom bonded to four different substituents – that can adopt either of two configurations that can be labeled as either an "R" or "S" configuration. As a result, the above chemical structure discloses ten different possible stereoisomers with the following configurations:

1. SRRR	6. SRSS
2. RSSS	7. RSRR
3. SRRS	8. RRSS
4. RSSR	9. SSSS
5. SRSR	10. RRRR

105. Forest was, and its successor-in-interest Allergan is, the holder of NDA No. 21-742 for Bystolic. The active ingredient in Bystolic is a mixture of two of the above ten stereoisomers: the SRRR and RSSS stereoisomers (i.e., nos. 1 and 2, above). The mixture of these two stereoisomers is referred to as nebivolol, and both are present in Bystolic as a hydrochloride salt.

106. Forest obtained two additional patents on Bystolic, U.S. Patent Nos. 6,545,040 ("the '040 Patent") and 5,759,580 ("the '580 Patent"). Forest certified to the FDA that the '040 and '580 Patents covered Bystolic, and the FDA listed those patents in the Orange Book.

B. Forest's Bystolic Patents

107. The '580 Patent issued on June 2, 1998 and expired seventeen years later, on June 2, 2015. Accordingly, the '580 Patent afforded Forest no protection from generic competition for Bystolic beyond June 2, 2015.

108. The '040 Patent issued from United States Application Serial No. 07/825,488 ("the '488 Application") filed on January 24, 1992, and was originally set to expire on April 8, 2020. However, on September 30, 2011, the PTO granted a patent term extension of 618 days past April 8, 2020, resulting in an expiration date of December 17, 2021. To understand the impact of prosecution of the '488 Application at the PTO on the scope of the issued claims in the '040 Patent, it is important to understand the effect of the choice of a transition phrase in a patent claim.

109. "A patent claim typically has three parts: the preamble, the transition, and the body." Donald S. Chisum, CHISUM ON PATENTS § 8.06[1](b) (2003). "The preamble is an introductory phrase that may summarize the invention, its relation to the prior art, or its intended use or properties." *Id*. § 8.06[1](b)[i]. "The transition is a phrase connecting the preamble to the body of the claim. The content of the phrase may indicate whether the elements stated in the body are 'open' or 'closed.'" *Id*. § 8.06[1](b)[ii]. "The body of the claim is the recitation or listing of the elements and limitations which define the product or process to be encompassed within the patent monopoly." *Id*. § 8.06[1](b)[iii].

110. There are three commonly used transitional phrases: "comprising," "consisting of," and "consisting essentially of." *Id*. § 8.06[1](b)[ii]; *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006). These are "terms of art in patent law that 'define the scope of the claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.'" *Id*. (quoting the Manual of Patent Examining Procedures).

111. The phrase "comprising" signifies that the claim is "open" to the addition of unrecited components or steps. *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007). For example, a claim reciting a product "comprising" three ingredients A, B, and C encompasses a product composed of A, B, C, and D (i.e., the addition of D to the A-B-C combination does not avoid infringement).

112. The claims originally filed in the application that issued as the '040 Patent employed the open transition "comprising." For example, originally-filed claim 19 of the '040 Patent application covered pharmaceutical compositions "comprising" a "pharmaceutically acceptable carrier" and the SRRR and RSSS stereoisomers of nebivolol. The use of the open transition "comprising" meant that original claim 19 covered formulations having the SRRR and

RSSS stereoisomers of nebivolol, even if the formulations also included some or all of the other eight unclaimed stereoisomers of nebivolol. The PTO examiner thus rejected those claims based upon the prior art '362 Patent described above. The examiner concluded that the '362 Patent described mixtures of various of the stereoisomers described above, and thus were covered by pending claim 19.

113. In response, the applicants admitted that the '362 Patent taught "undefined mixtures that may include the presently claimed compounds in admixture with other stereoisomers of the Base Compound." The '362 Patent taught an enumerated list of compounds, including compounds named Compound 84 and Compound 87. More specifically, the applicants admitted that "Compound 84 . . . is an undefined mixture of the RSRR, RSSS, SRSS and SRRR isomers, and Compound 87 . . . is an undefined mixture of the RSRS, RSSR, and SRRS isomers."

114. In hopes of overcoming the rejection, the applicants narrowed the claims by substituting new claims utilizing the transition "consisting essentially of" rather than "comprising." In doing so, the applicants emphasized that the purpose of the amendment was to distinguish their claims from the undefined mixtures of other nebivolol isomers disclosed in the Prior Art '362 Patent:

> Claims 18 and 19 have been rewritten as new Claims 25 and 26. Claim 25 recites "A composition consisting essentially of the compound . . .", and Claim 26 recites "A pharmaceutical composition consisting essentially of . . . [the two compounds (a) and (b)]". This amendment is being made to more clearly distinguish the claimed invention over the prior art ['362 Patent] which, as is explained in detail below, discloses undefined mixtures that may include the presently claimed compounds in admixture with other stereoisomers of [nebivolol]. Favorable consideration of the amended claims is respectfully requested.

115. The transition "consisting essentially of" in a patent claim narrows the claim relative to "comprising." *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir.

2003). "[W]ith respect to a 'consisting essentially of' claim, there is no infringement where the accused product contains additional, unclaimed ingredients that materially affect the basic and novel properties of the invention." *Yoon Ja Kim v. Conagra Foods, Inc.*, 465 F.3d 1312, 1320-21 (Fed. Cir. 2006). Thus, for a claim reciting a product "consisting essentially of" ingredients A, B, and C, the addition of unrecited ingredient D will avoid infringement if D has a material effect on the basic and novel properties of the claimed invention.

116. The PTO examiner, however, was not persuaded that the use of the "consisting essentially of" transition distinguished the then-pending claims from the '362 Patent. He therefore maintained his rejection of the claims.

117. The applicants for the '040 Patent again argued that it was impossible to tell from the '362 Patent which stereoisomers, and in what amounts, were definitely present in the disclosed mixtures: "There is no way that one can determine from the teachings of the patent the specific stereoisomeric configuration of [the prior art '362 Patent's] compound Nos. 84 and 87." The Examiner continued to maintain his rejections and ultimately issued a final rejection of the "consisting essentially of" Claims 25 and 26, as anticipated by the '362 Patent (that is, the '362 Patent described the same compounds). He also rejected the claims as obvious, because the application claimed compounds that were obvious variants of the compounds taught by the '362 Patent. Under 35 U.S.C. §103, a patent will not be granted if it contains only obvious differences from the prior art. In other words, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time a patent application is filed, a patent application will be rejected.

118. The applicants for the '040 Patent appealed the examiner's final anticipation and obviousness rejections to the Board of Patent Appeals and Interferences ("the Board"). In their

brief, the applicants continued to argue that it was impossible to say exactly which stereoisomers (and how much of them) were present in Compound 84 of the prior art '362 Patent, but that the "possible" stereoisomers present in unknown amounts were RSRR, RSSS, SRRR and SRSS. During the course of briefing the appeal to the Board, the Examiner dropped the anticipation rejection.

119. The Board nevertheless addressed the anticipation issue and made certain findings and conclusions regarding the relationship between then-pending Claim 26 and Compound 84 of the '362 Patent. Specifically, the Board concluded:

> [The '362 Patent's] disclosure of compound 84, together with its designation "AB," appears to describe the individual RSSS, SRRR, RSRR and SRSS stereoisomers "just as surely as if they were identified in the reference by name."

120. The Board then determined that the "consisting essentially of" transition in then-pending Claim 26 caused the claim to cover the undefined mixture of isomers in the Prior Art '362 Patent:

> It is well settled that "the phrase 'consisting essentially of' limits the scope of a claim to the specified ingredients and those that do not materially affect the basic and novel characteristic(s) of a composition." Here, a basic and novel characteristic of the pharmaceutical composition of claim 26 is its blood pressure reducing or antihypertensive effect. Thus, claim 26 is open to ingredients that do not materially affect its antihypertensive activity. [The prior art '362 Patent's] antihypertensive compound 84 is a mixture of four stereoisomers: RSSS, SRRR, RSRR and SRSS. ***Because the RSSR and SRSS stereoisomers do not materially affect blood pressure reducing or antihypertensive activity, it appears that they are not excluded from the composition of claim 26***.

(internal citation omitted, and emphasis added).

121. Accordingly, the Board ordered the Examiner to reconsider his withdrawal of the anticipation rejection based on the Prior Art '362 Patent:

> Specifically, the examiner should consider whether claim 26 'reads on' [the '362 Patent's] compound 84 taking into account the appropriate principles of claim interpretation and the foregoing remarks.

The very clear upshot of the Board's decision was that the claims of the '488 Application were not patentable unless the claims excluded the unclaimed stereoisomers, particularly the RSSR and SRSS stereoisomers.

122. On remand from the Board, the applicants for the '040 Patent did not even attempt to argue against anticipation in view of the Board's opinion. Alternatively, they further narrowed their claims by replacing "consisting essentially of" with "consisting of" in new Claims 27 and 28. Based on that change, applicants argued that the new "consisting of" limitation excluded the undefined mixture of possible stereoisomers in the '362 Patent:

> Applicants respectfully submit that the claims, as amended, are patentable over [the prior art '362 Patent]. Applicants submit that neither a composition consisting of the RSSS enantiomer, nor a composition consisting of the RSSS enantiomer and its enantiomer the SRRR enantiomer, are disclosed in [the '362 Patent]. [The '362 Patent] discloses the base compound, as an undefined mixture of stereoisomers, as compound 84 (designated as "AB") and 87 (designated as "AA"), shown in the table in Col. 21 of the patent.

123. The applicants expressly noted that "Compound 84 [of the prior art '362 Patent] is an undefined mixture of the RSRR, RSSS, SRSS and SRRR isomers, and Compound 87 . . . is an undefined mixture of the RSRS, RSSR, and SRRS isomers." They argued that the new "consisting of" language excluded compounds containing such additional isomers:

> [I]t is clear that the cited [the '362 Patent] discloses neither a composition consisting of the RSSS enantiomer of the base compound, nor a composition consisting of the RSSS and SRRR enantiomers.

124. Applicants did not differentiate their claims based on any particular amount or source of possible unrecited stereoisomers in the "undefined mixture" of the '362 Patent.

125. The phrase "consisting of" is the narrowest of the transitions and it "signifies restriction and exclusion of unrecited steps or components." Manual of Patent Examining Procedures § 2111.03; *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004). In light of the Board's reasoning and the applicants' comments and amendments, it is clear that the narrowing amendment was intended to and did exclude the presence of the unclaimed stereoisomers, particularly the RSSR and SRSS stereoisomers (*i.e.*, the claims do not cover formulations containing the unclaimed stereoisomers, especially the RSSR and SRSS stereoisomers).

126. The Examiner then allowed the "consisting of" Claims 27 and 28, which ultimately issued as Claims 2 and 3 of the '040 Patent in 2003.

127. Subsequently, the '040 Patent was subjected to reexamination proceedings and a reexamination certificate was issued in 2009.

C. Generic Competitors' ANDAs for Generic Versions of Bystolic.

128. Hetero, Torrent, Alkem, Indchemie, Glenmark, Amerigen, and Watson were the first generic manufacturers to file ANDAs with the FDA containing Paragraph IV certifications regarding Bystolic patents. For example, in letters granting final approval to their ANDAs, the FDA noted that each was "one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Nebivolol Tablets."[33]

[33] *See, e.g.*, 11/27/2015 Letter from FDA to Watson, at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf (last visited September 13, 2020); 5/27/2017 Letter from FDA to Glenmark, at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203821Orig1s000ltr.pdf (last visited September 13, 2020); 6/24/2015 Letter from FDA to Alkem, at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203741Orig1s000ltr.pdf (last visited September 13, 2020).

129. Since the Generic Competitors were the first companies to file substantially complete ANDAs with Paragraph IV certifications, they each stood to receive 180 days of marketing exclusivity during which the FDA would not give final approval to any later ANDA filer's generic equivalent of Bystolic.

130. Forest received the Generic Competitors' Paragraph IV notice letters on the following dates:

Torrent:	February 2, 2012[34]
Indchemie:	February 3, 2012[35]
Alkem:	February 3, 2012[36]
Watson:	February 13, 2012[37]
Amerigen:	February 16, 2012[38]
Hetero:	February 17, 2012[39]
Glenmark:	February 20, 2012[40]

131. As Paragraph IV certifications, these notice letters were required to include a detailed statement of the factual and legal bases as to why the '040 Patent was invalid, unenforceable, and/or not infringed by their ANDA products. The Paragraph IV notice letters also were required to include an offer of confidential access to each Generic Competitor's ANDA under the Hatch-Waxman Act.

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[34] *Forest Labs. v. Torrent Pharms. Ltd.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1 ¶ 93).

[35] *Forest Labs. v. Indchemie Health Specialties PVT*, 12-cv-01855 (N.D. Ill. Mar. 14, 2012) (ECF No. 1 ¶ 22).

[36] *Id.* ¶ 38.

[37] *Forest Labs. v. Torrent Pharms. Ltd.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1 ¶ 108).

[38] *Id.* ¶ 123.

[39] *Id.* ¶ 138.

[40] *Id.* ¶ 153.

132. The notice letters gave rise to a potential cause of action for patent infringement, thereby allowing Forest to file suit against the Generic Competitors under the Hatch-Waxman Act.

D. The Bystolic Patent Litigation.

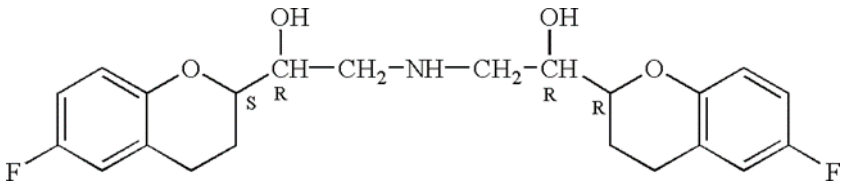
133. On March 13, 2012, in response to the Paragraph IV certification letters, Forest filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Hetero, Torrent, Glenmark, Amerigen, and Watson.[41]

134. On March 14, 2012, in response to the Paragraph IV certification letters, Forest filed a patent infringement lawsuit in the United States District Court for the Northern District of Illinois against Indchemie and Alkem.[42]

135. By order of the Judicial Panel for Multidistrict Litigation, these cases were consolidated into *In re Nebivolol Patent ('040) Litigation*, 12-cv-5026 (N.D. Ill. June 12, 2012) (ECF No. 1) (hereafter referred to as the "Nebivolol Patent Litigation").

136. Forest could not prevail in the Nebivolol Patent Litigation. The sole independent claim asserted by Forest in the Bystolic Patent Litigation was claim 2, as shown below:

> 2. A pharmaceutical composition consisting of a pharmaceutically acceptable carrier and, as active ingredients:
>
> (a) the blood pressure reducing compound [2S,αR, 2′R,α′R]-α,α′- [iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:

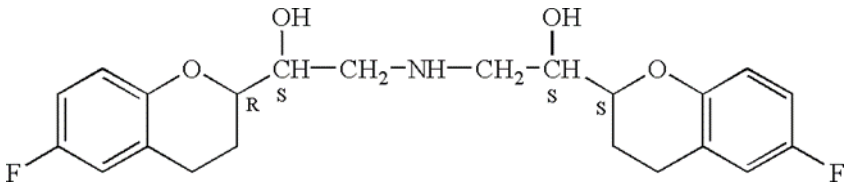


[41] *Forest Labs. v. Torrent Pharms. Ltd.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1).

[42] *Forest Labs. v. Indchemie Health Specialties PVT*, 12-cv-01855 (N.D. Ill. Mar. 14, 2012) (ECF No. 1).

or a pharmaceutically acceptable acid addition salt thereof; and

(b) the compound [2R,αS,2′S,α′S]-α,α′-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:



or a pharmaceutically acceptable acid addition salt thereof.

See ’040 Patent at 11:33-12:22. Thus, claim 2 was limited to a pharmaceutical composition consisting of a pharmaceutically acceptable carrier and, as active ingredients, SRRR-nebivolol and RSSS-nebivolol (or pharmaceutically acceptable acid addition salts).

137. The Generic Competitors were well aware of the prosecution history of the ’040 Patent and the narrowing amendments the applicants had made. During claim construction proceedings in the Nebivolol Patent Litigation, they correctly argued that the term “consisting of” in claim 2 of the ’040 Patent “excludes any unrecited stereoisomers of nebivolol.” The Generic Competitors’ products did not infringe because they included at least small amounts of the unrecited stereoisomers of nebivolol, including the RSSR and SRSS stereoisomers.

138. Early in the Bystolic Patent Litigation, the Generic Competitors pressed the argument that the “consisting of” transition precluded the use of a plurality of inactive ingredients. Their position was premised on the argument that (1) a “pharmaceutically acceptable carrier” referred to an individual inactive ingredient in a pharmaceutical formulation; (2) the transition “closed” the claim to unrecited inactive ingredients; and (3) therefore, the claims did not cover formulations having two or more inactive ingredients. At least one other court has construed “pharmaceutically acceptable carrier” to mean “a conventional pharmaceutically acceptable

excipient or additive." *See Schering Corp. v. Mylan Pharms., Inc.*, No. 2:10-cv-03085, 2011 WL 2446563, at *11 (D.N.J. Jun. 15, 2011). To the extent this interpretation applied in the Nebivolol Patent Litigation, and for this additional reason, the Generics' products did not infringe.

139. As a result, Forest could not prevail in proving literal infringement of the asserted claims of the '040 Patent. A claim is literally infringed if the accused product or process includes all elements or limitations of the claim. *Signtech U.S.A. v. Vutek, Inc*. 174 F.3d 1352 (Fed. Cir. 1999); *Builders Concrete, Inc. v. Bremerton Concrete Products*, 757 F.2d 255, 257 (Fed. Cir. 1985).In light of the prosecution history of the '040 Patent, Forest also could not prevail under the doctrine of equivalents theory of infringement. If a patent applicant avoids including the literal language of another patent's claims by making unimportant and insubstantial changes, the applicant could be liable under the doctrine of equivalents. *Graver Tank & Mfg. Co. v. Linde Air Products Co*., 339 U.S. 605, 606 (1950). *Warner-Jenkinson Co. v. Hilton Davis Chemical Co*., 117 S. Ct. 1040 (S.Ct. 1996). The test for whether an element in the alleged infringer's product or process is equivalent to a claimed element is whether the difference between the two are insubstantial to one of ordinary skill in the art. *See*, *e.g.*, *Hilton Davis Chemical Co. v. Warner-Jenkinson Co*., 62 F.3d 1512, 1517 (Fed. Cir. 1995); aff'd sub nom. *Warner-Jenkinson Co. v. Hilton Davis Chemical Co*., 520 U.S. 17 (1997).

140. In addition, Forest's defenses against the invalidity argumentsconcerning the asserted claims of the '040 Patent were weak and it could not have prevailed against those arguments.

141. As the Board explained during the prosecution of the '040 Patent:

> [The '362 Patent's] disclosure of compound 84, together with its designation "AB," appears to describe the individual RSSS, SRRR, RSRR and SRSS stereoisomers "just as surely as if they were identified in the reference by name."

142. The ’362 Patent was prior art to the ’040 Patent. In light of the ’362 Patent’s essentially explicit teaching of a mixture of “the individual RSSS, SRRR, RSRR and SRSS stereoisomers” of nebivolol, the asserted compositions in the ’040 Patent were anticipated by, or obvious in view of, the prior art, including other pertinent prior art such as Van de Water et al., Pharmacological and Hemodynamic Profile of Nebivolol, a Chemically Novel, Potent, and Selective B1-Adrenergic Antagonist, Journal of Cardiovascular Pharmacology, 11, No. 5, 552-563 (1988). Any purported evidence of secondary indicia of non-obviousness was insufficient to overcome the clear prima facie obviousness of the claims.

143. On November 7, 2013, the parties to the Nebivolol Patent Litigation filed a stipulation that “[t]he filing of ANDA No. 203683 was a technical act of infringement of the '040 Patent under 35 U.S.C. § 271(e)(2)(A). No decision of the Court has been obtained by either party regarding the presumptive validity or enforceability of the '040 Patent and/or whether the product described by ANDA No. 203683 infringes that patent” and “[a]ll other claims and defenses set forth in Plaintiffs' and Actavis's pleadings against each other, including the allegations and averments contained therein, are hereby dismissed, without prejudice.” Further, the stipulation provided that, “Actavis, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic tablet products containing 2.5 milligrams, 5 milligrams, 10 milligrams, or 20 milligrams of nebivolol hydrochloride per tablet that are the subject of ANDA No. 203683 during the life of the '040 Patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs, unless all of the asserted claims of the '040 Patent are found invalid or unenforceable by

a court decision from which no appeal has been or can be taken, other than a petition for a writ of certiorari to the U.S. Supreme Court." The stipulation and order for dismissal without prejudice was entered by the Court on December 16, 2013.

E. Forest's Unlawful Pay-for-Delay Deals with Generic Competitors.

144. Starting on October 24, 2012, Forest began entering into settlements with Generic Competitors to resolve the Nebivolol Patent Litigation. Forest's internal and external counsel have conceded that each of these settlements also included "side deals," as follows:

To: 'Malester, Ann'[]; Newborn, Steven[steven.newborn@weil.com]
From: Agovino, Eric
Sent: Tue 3/4/2014 7:47:28 PM
Importance: Normal
Subject: RE: Namenda settlements
Received: Tue 3/4/2014 7:47:00 PM
EXECUTED Forest-Hetero Settlement and License Agreement.pdf
EXECUTED Term Sheet (Hetero).pdf

We entered into settlement agreements with the following defendants:

1) Hetero

2) Torrent

3) Alkem

4) Indchemie

5) Glenmark

6) Amerigen

7) Actavis

All had side deals (one side was struck with Alkem, which is a related company with Indchemie).

Attached are the Hetero agreements.

From: Malester, Ann [mailto:Ann.Malester@weil.com]
Sent: Tuesday, March 04, 2014 9:15 AM
To: Agovino, Eric; Newborn, Steven
Subject: RE: Namenda settlements

Eric,

Before we engage in any discussions with the FTC on the Namenda agreements, we think it would be prudent for us to review all of the Bystolic settlement and licensing agreements as well as the side agreements with those generic companies. Could you put together the same type of information for Bystolic as you sent us for Namenda?

Thanks so much, Ann

145. These side deals also were listed in Forest's Merger Agreement with Actavis, as "material contracts" that on information and belief "involve payments . . . of consideration in excess of $15,000,000."[43] In addition, Forest admitted that it had reimbursed "certain of the Settling Defendants' legal costs in connection with the patent litigation."[44] Accordingly, on information and belief, Forest paid each Generic Competitor at least $15,000,000, and likely more, in reverse payments to resolve the Nebivolol Patent Litigation and induce the Generic Competitors to walk away from the patent fight.

146. The Hetero pay-for-delay deal included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Hetero USA Inc. and Hetero Labs Ltd. dated October 24, 2012," plus payment for Hetero's litigation costs, and a "FINAL TERM SHEET between Hetero Drugs Ltd. and Forest Laboratories Ireland Ltd. dated October 5, 2012, in connection with the settlement of BYSTOLIC patent dispute."[45]

147. On information and belief, in addition to the monies Forest paid Hetero for Hetero's litigation costs, pursuant to the "FINAL TERM SHEET," Forest paid Hetero more than $15,000,000.

148. The Torrent pay-for-delay deal included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. dated November 21, 2012," plus payment for

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[43] *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-cv-07488 (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 69).

[44] *See* https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm (last visited September 13, 2020).

[45] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 179).

Torrent's litigation costs, and a "PATENT ASSIGNMENT AGREEMENT between Torrent Pharmaceuticals Ltd and Forest Laboratories Holdings Ltd. dated November 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[46]

149. On information and belief, in addition to the monies Forest paid Torrent for Torrent's litigation costs, pursuant to the "PATENT ASSIGNMENT AGREEMENT," Forest paid Torrent more than $15,000,000.

150. The Alkem pay-for-delay deal included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem Laboratories Ltd. dated November 27, 2012," plus payment for Alkem's litigation costs, and a "TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute." Alkem and Forest also entered into an "AMENDMENT NO. 1 TO SETTLEMENT AGREEMENT . . . on January 9, 2013."[47]

151. On information and belief, in addition to the monies Forest paid Alkem for Alkem's litigation costs, pursuant to the Alkem "TERM SHEET," Forest paid Alkem more than $15,000,000.

152. The Indchemie pay-for-delay deal included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Indchemie Health Specialties Private Ltd. dated November 27, 2012," plus payment for Indchemie's litigation costs, and a "TERM SHEET between Alkem Laboratories Ltd, Indchemie Health Specialties Private Ltd,

[46] *Id*.

[47] *Id*.

and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute."[48]

153. On information and belief, in addition to the monies Forest paid Indchemie for Indchemie's litigation costs, pursuant to the Indchemie "TERM SHEET," Forest paid Indchemie more than $15,000,000.

154. The Glenmark pay-for-delay deal included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Glenmark Generics Inc., USA and Glenmark Generics Ltd. dated December 21, 2012," plus payment for Glenmark's litigation costs, and a "COLLABORATION AND OPTION AGREEMENT between Glenmark Pharmaceuticals S.A. and Forest Laboratories Holdings Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[49]

155. On information and belief, in addition to the monies Forest paid Glenmark for Glenmark's litigation costs, pursuant to the "COLLABORATION AND OPTION AGREEMENT," Forest paid Glenmark more than $15,000,000.

156. The Amerigen pay-for-delay deal included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013," plus payment for Amerigen's litigation costs, and a "BINDING TERM SHEET COLLABORATION AGREEMENT between Forest Laboratories, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013, in connection with the settlement of BYSTOLIC patent dispute."[50]

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[48] *Id*.

[49] *Id*.

[50] *Id* at 180.

157. On information and belief, in addition to the monies Forest paid Amerigen for Amerigen's litigation costs, pursuant to the "BINDING TERM SHEET COLLABORATION AGREEMENT," Forest paid Amerigen more than $15,000,000.

158. The Watson pay-for-delay deal included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Actavis, Inc. dated November 6, 2013," plus payment for Watson litigation costs, and "(a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between [Watson] and Moksha8, Inc. dated November 4, 2013, in connection with the settlement of BYSTOLIC patent dispute."[51]

159. On information and belief, in addition to the monies Forest paid Watson for Watson's litigation costs, pursuant to the "(a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between [Watson] and Moksha8, Inc.," Forest paid Watson more than $15,000,000.

160. On information and belief, the value of each pay-for-delay deal exceeded Forest's avoided litigation costs.

161. In exchange for these pay-for-delay deals, each Generic Competitor agreed not to compete with Forest in the Bystolic market, in which Forest had a monopoly, for as long as all others also agreed not to compete, until September 17, 2021 (a mere three months prior to expiry of the '040 Patent).[52]

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[51] *Id*.

[52] https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/ R17.htm.

162. The purpose and effect of the pay-for-delay deals were to delay Forest from having to face lower-priced generic competition for years.

163. But for the pay-for-delay deals, the Generic Competitors would have been ready, able, and willing to launch their generic versions of Bystolic much earlier.

164. Specifically, the Generic Competitors would have launched by the later of: (a) June 2015, which was the expiry of the only other patent that Forest contended covered Bystolic (the '580 Patent), or (b) the date their ANDAs were finally approved.[53]

165. By operation of the CLPs, if just one Generic Competitor launched a generic version of Bystolic prior to September 17, 2021, pursuant to any of the three above scenarios, all other Generic Competitors would have entered the market.

166. By about October 2012, when Forest and the Generic Competitors began making pay-for-delay deals, Bystolic was generating hundreds of millions of dollars per year in revenues for Forest. Forest would have lost a substantial portion of that revenue stream in the event any of the Generic Competitors were to prevail on non-infringement or other defenses, or in the event that Forest had not induced the Generic Competitors with pay-for-delay deals to agree to delay launching generic Bystolic. Thus, Forest had enormous incentives to avoid competition from the Generic Competitors by entering into pay-for-delay deals.

167. Forest's willingness to provide large payments to each Generic Competitor in exchange for a multi-year delay in competition amounted to an agreement to share with the Generic Competitors the monopoly profits from sales of branded Bystolic at supra-competitive levels.

[53] *See* ¶ 6, *supra*.

VII. EFFECTS OF DEFENDANTS' VIOLATIONS OF THE ANTITRUST LAWS

168. As a result of Defendants' unlawful concerted action, competition in the Bystolic market has been reduced or eliminated and prices for Bystolic have been maintained at supra-competitive levels. Direct purchasers in the United States have, therefore, been deprived of the benefit of price competition in the Bystolic market.

169. During the Class Period, Plaintiff (by way of assignment) and Class Members directly purchased Bystolic. As a result of Defendants' anticompetitive conduct, Plaintiff and Class Members paid more for Bystolic than they otherwise would have, and thereby sustained substantial losses and damages to their business and property in the form of overcharges. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

170. As alleged herein, but for the unlawful pay-for-delay agreements, generic competition would have entered the market much earlier than September 17, 2021.

171. The unlawful conduct of Defendants deprived Plaintiff and Class Members of the benefits of competition that the antitrust laws were designed to ensure.

172. Defendants' anticompetitive conduct is ongoing, and as a result, Plaintiff and Class Members continue to pay supra-competitive prices for Bystolic.

VIII. ANTITRUST IMPACT

173. During the class period, as a result of Defendants' illegal conduct, Plaintiff and Class Members were compelled to purchase substantial amounts of Bystolic directly from Forest and others at supra-competitive, artificially inflated prices. Those prices were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) the price of branded Bystolic was artificially inflated by Defendants' illegal conduct; (2) Plaintiff and Class Members were deprived of the opportunity, which they would have taken, to purchase lower-priced generic versions of Bystolic instead of brand Bystolic sooner; and/or (3) Plaintiff and Class

Members would have paid lower prices for generic Bystolic than the prices they actually paid for generic Bystolic.

174. As a consequence, Plaintiff and Class Members have sustained substantial losses and damages to their business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

IX. IMPACT ON INTERSTATE TRADE AND COMMERCE

175. During the relevant time period, Defendants manufactured, promoted, sold, and shipped Bystolic across state lines in an uninterrupted flow of interstate commerce.

176. As a direct result of the unlawful pay-for-delay deals, the Generic Competitors refrained from selling generic versions of Bystolic when they otherwise would have done so.

177. The unlawful monopolization in the Bystolic market, as alleged in this Complaint, has directly and substantially affected interstate commerce, as Defendants deprived Plaintiff and Class Members of the benefits of free and open competition in the purchase of Bystolic within the United States.

178. The effects of Defendants' anticompetitive conduct were intended to have and did have a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States.

X. MARKET POWER AND DEFINITION

179. The relevant geographic market is the United States and its territories and possessions.

180. At all relevant times, Defendants had monopoly power over Bystolic products because they had the power to maintain the price of the Bystolic they sold at supra-competitive

levels without losing substantial sales to other products prescribed and/or used for the same purposes as Bystolic.

181. "[T]he 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power'—namely, the power to charge prices higher than the competitive level."[54] And a firm that lacks monopoly power is not "likely to pay 'large sums' to induce 'others to stay out of its market.'"[55]

182. A small but significant non-transitory price increase for Bystolic by Defendants would not have caused a significant loss of sales to non-Bystolic products.

183. Bystolic does not exhibit significant, positive cross-elasticity of demand with respect to price with any non-Bystolic product. Indeed, Defendants have never lowered the price of Bystolic in response to the pricing of any non-Bystolic treatments for high blood pressure. In fact, Defendants substantially increased the price of Bystolic – by more than 60% – over the last five years.

184. Because of its labeling, Bystolic is differentiated from all non-Bystolic products.

185. Defendants needed to control only Bystolic, and no other products, in order to maintain the price of Bystolic profitably at supra-competitive prices. No non-Bystolic product ever rendered Defendants unable to profitably maintain or raise their prices of Bystolic without losing substantial sales.

186. Defendants also sold Bystolic at prices well-above marginal costs, and in excess of the competitive price, and, thus, enjoyed high profit margins.

[54] *Actavis*, 570 U.S. at 157 (citation omitted).
[55] *Id*.

187. Defendants have had, and exercised, the power to exclude and restrict competition to Bystolic.

188. Defendants, at all relevant times, enjoyed high barriers to entry with respect to competition to the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

189. Plaintiff alleges that the relevant market is the Bystolic market.

190. During the period relevant to this case, Defendants have been able to profitably maintain the price of Bystolic well-above competitive levels.

At all relevant times, Defendants' market share in the relevant market was and remains 100%, a substantial amount of monopoly power.

XI. CLASS ACTION ALLEGATIONS

191. Pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3), Plaintiff brings this action on behalf of a Direct Purchaser Class defined as follows:

> All persons in the United States and its territories that directly purchased Bystolic from July 9, 2016 until the effects of the Defendants' conduct cease.

192. Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

193. Members of the class are so numerous that joinder is impracticable. Plaintiff believes that the class is numerous and geographically dispersed throughout the United States such that joinder of all Class Members is impracticable. Further, the class is readily identifiable from information and records maintained by Defendants.

194. Plaintiff's claims are typical of the claims of Class Members. Plaintiff's interests are not antagonistic to the claims of the other Class Members, and there are no material conflicts

with any other members of the class that would make class certification inappropriate. Plaintiff and Class Members were damaged by the same wrongful conduct of Defendants.

195. Plaintiff will fairly and adequately protect and represent the interests of the class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the class.

196. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation and who have particular experience with class action litigation involving alleged violations of antitrust law.

197. Questions of law and fact common to Class Members predominate over questions that may affect only individual Class Members because Defendants have acted on grounds generally applicable to the entire class, thereby determining damages with respect to the class as a whole is appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

198. The common legal and factual questions, which do not vary from Class Member to Class Member and which may be determined without reference to individual circumstances of any Class Member, include, but are not limited to, the following:

(a) whether Defendants' anticompetitive scheme suppressed generic competition to Bystolic;

(b) whether there exist cognizable, non-pretextual procompetitive justifications for those parts of Defendants' challenged conduct for which such justifications may be offered, and which Defendants' challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the Bystolic market;

(c) whether direct proof of monopoly power is available, and, if yes, whether it is sufficient to prove monopoly power without the need to also define a relevant market;

(d) to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

(e) what is a reasonable estimate of the amount of delay the Defendants' unlawful agreements and monopolistic, unfair, and unjust conduct caused;

(f) whether Defendants' scheme, in whole or in part, has substantially affected interstate commerce;

(g) whether Defendants' scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiff and Class Members in the form of overcharges; and

(h) what is the amount of overcharges paid by the class in the aggregate.

199. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a larger number of similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweigh potential difficulties in management of this class action.

200. Plaintiff knows no specific difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XII. CLAIMS FOR RELIEF

COUNT 1 – VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDANTS AND HETERO)

201. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

202. Defendants have violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by engaging in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce.

203. On or about October 5 2012, Forest and Hetero entered into illegal contracts, combinations and conspiracies in the withholding of trade under which Forest agreed to make substantial pay-for-delay payments to Hetero in exchange for Hetero's agreement to delay bringing its generic Bystolic to market until September 17, 2021.

204. The purpose and effect of these pay-for-delay deals were to: (a) allocate to Forest 100% of Bystolic sales in the United States until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thus protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supra-competitive levels, the price Plaintiff and Class Members paid for Bystolic.

205. The Hetero pay-for-delay agreements were unlawful, and the reverse payments were large and unjustified.

206. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Hetero that outweighs their harmful effect. Even if there were some conceivable justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

207. As a direct, proximate, foreseeable, and intended result of the Hetero reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and Class Members were harmed and suffered overcharge damages as described above. Specifically, without the pay-for-delay dealings, Hetero would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby

reasonable parties in the position of Forest and Hetero would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Hetero side deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Hetero and Forest would have applied to all earlier-settling Generic Competitors, if any.

COUNT 2 – VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDANTS AND TORRENT)

208. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

209. Defendants have violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by engaging in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce.

210. On or about November 21, 2012, Forest and Torrent entered into illegal contracts, combinations and conspiracies in the withholding of trade under which Forest agreed to make substantial pay-for-delay payments to Torrent in exchange for Torrent's agreement to delay bringing its generic Bystolic to market until September 17, 2021.

211. The purpose and effect of these pay-for-delay deals were to: (a) allocate to Forest 100% of Bystolic sales in the United States until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thus protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supra-competitive levels, the price Plaintiff and Class Members paid for Bystolic.

212. The Torrent pay-for-delay agreements were unlawful, and the reverse payments were large and unjustified.

213. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Torrent that outweighs their harmful effect. Even if there were some conceivable justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

214. As a direct, proximate, foreseeable, and intended result of the Torrent reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and Class Members were harmed and suffered overcharge damages as described above. Specifically, without the pay-for-delay dealings, Torrent would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Torrent would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Torrent side deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Torrent and Forest would have applied to all earlier-settling Generic Competitors, if any.

COUNT 3 – VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDANTS AND ALKEM)

215. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

216. Defendants have violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by engaging in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce.

217. On or about November 27, 2012, Forest and Alkem entered into illegal contracts, combinations and conspiracies in the withholding of trade under which Forest agreed to make

substantial pay-for-delay payments to Alkem in exchange for Alkem's agreement to delay bringing its generic Bystolic to market until September 17, 2021.

218. The purpose and effect of these pay-for-delay deals were to: (a) allocate to Forest 100% of Bystolic sales in the United States until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thus protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supra-competitive levels, the price Plaintiff and Class Members paid for Bystolic.

219. The Alkem pay-for-delay agreements were unlawful, and the reverse payments were large and unjustified.

220. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Alkem that outweighs their harmful effect. Even if there were some conceivable justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

221. As a direct, proximate, foreseeable, and intended result of the Alkem reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and Class Members were harmed and suffered overcharge damages as described above. Specifically, without the pay-for-delay dealings, Alkem would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Alkem would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Alkem side deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Alkem and Forest would also have applied to all earlier-settling Generic Competitors, if any.

COUNT 4 – VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDANTS AND INDCHEMIE)

222. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

223. Defendants have violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by engaging in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce.

224. On or about November 27, 2012, Forest and Indchemie entered into illegal contracts, combinations and conspiracies in the withholding of trade under which Forest agreed to make substantial pay-for-delay payments to Indchemie in exchange for Indchemie's agreement to delay bringing its generic Bystolic to the market until September 17, 2021.

225. The purpose and effect of these pay-for-delay deals were to: (a) allocate to Forest 100% of Bystolic sales in the United States until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thus protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supra-competitive levels, the price Plaintiff and Class Members paid for Bystolic.

226. The Indchemie pay-for-delay agreements were unlawful, and the reverse payments were large and unjustified.

227. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Indchemie that outweighs their harmful effect. Even if there were some conceivable justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

228. As a direct, proximate, foreseeable, and intended result of the Indchemie reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and Class Members were

harmed and suffered overcharge damages as described above. Specifically, without the pay-for-delay dealings, Indchemie would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Indchemie would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Indchemie side deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Indchemie and Forest would have applied to all earlier-settling Generic Competitors, if any.

COUNT 5 – VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDANTS AND GLENMARK)

229. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

230. Defendants have violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by engaging in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce.

231. On or about December 21, 2012, Forest and Glenmark entered into illegal contracts, combinations and conspiracies in the withholding of trade under which Forest agreed to make substantial pay-for-delay payments to Glenmark in exchange for Glenmark's agreement to delay bringing its generic Bystolic to market until September 17, 2021.

232. The purpose and effect of these pay-for-delay deals were to: (a) allocate to Forest 100% of Bystolic sales in the United States until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thus protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supra-competitive levels, the price Plaintiff and Class Members paid for Bystolic.

233. The Glenmark pay-for-delay agreements were unlawful, and the reverse payments were large and unjustified.

234. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Glenmark that outweighs their harmful effect. Even if there were some conceivable justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

235. As a direct, proximate, foreseeable, and intended result of the Glenmark reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and Class Members were harmed and suffered overcharge damages as described above. Specifically, without the pay-for-delay dealings, Glenmark would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Glenmark would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Glenmark side deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Glenmark and Forest would also have applied to all earlier-settling Generic Competitors, if any.

COUNT 6 – VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDANTS AND AMERIGEN)

236. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

237. Defendants have violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by engaging in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce.

238. On or about July 18, 2013, Forest and Amerigen entered into illegal contracts, combinations and conspiracies in the withholding of trade under which Forest agreed to make substantial pay-for-delay payments to Amerigen in exchange for Amerigen's agreement to delay bringing its generic Bystolic to market until September 17, 2021.

239. The purpose and effect of these pay-for-delay deals were to: (a) allocate to Forest 100% of Bystolic sales in the United States until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thus protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supra-competitive levels, the price Plaintiff and Class Members paid for Bystolic.

240. The Amerigen pay-for-delay agreements were unlawful, and the reverse payments were large and unjustified.

241. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Amerigen that outweighs their harmful effect. Even if there were some conceivable justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

242. As a direct, proximate, foreseeable, and intended result of the Amerigen reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and Class Members were harmed and suffered overcharge damages as described above. Specifically, without the pay-for-delay dealings, Amerigen would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Amerigen would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Amerigen side deal and other reverse

payments. In addition, by operation of the CLPs, any earlier license date agreed to between Amerigen and Forest would have applied to all earlier-settling Generic Competitors, if any.

COUNT 7 – VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDANTS AND WATSON)

243. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

244. Defendants have violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by engaging in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce.

245. On or about November 1, 2013, Forest and Watson entered into illegal contracts, combinations and conspiracies in the withholding of trade under which Forest agreed to make substantial pay-for-delay payments to Watson in exchange for Watson's agreement to delay bringing its generic Bystolic to the market until September 17, 2021.

246. The purpose and effect of these pay-for-delay deals were to: (a) allocate to Forest 100% of Bystolic sales in the United States until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thus protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supra-competitive levels, the price Plaintiff and Class Members paid for Bystolic.

247. The Watson pay-for-delay agreements were unlawful, and the reverse payments were large and unjustified.

248. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Watson that outweighs their harmful effect. Even if there were

some conceivable justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

249. As a direct, proximate, foreseeable, and intended result of the Watson reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and Class Members were harmed and suffered overcharge damages as described above. Specifically, without the pay-for-delay dealings, Watson would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Watson would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Watson side deal and other reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between Watson and Forest would have applied to all earlier-settling Generic Competitors, if any.

COUNT 8 – VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDENTS AND HETERO)

250. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

251. Defendants possessed, and will continue to possess, substantial market power (*i.e.*, monopoly power) in the relevant market at all times prior to September 17, 2021. Defendants possessed and will continue to possess the power to (1) prevent prices from falling in the relevant market; (2) exclude competitors from the relevant market; and (3) control and maintain the prices in the relevant market.

252. Through pay-for-delay deals, Forest and Hetero conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to delay and prevent market entry of generic Bystolic. Such agreements gave Forest 100% of Bystolic market sales in the United

States until September 17, 2021; withheld the availability of generic versions of Bystolic to prevent any generic competition until September 17, 2021; and fixed and maintained the price Plaintiff and Class Members paid for Bystolic at supra-competitive levels.

253. The goal, purpose, and effect of Forest and Hetero's scheme was to maintain and extend Forest's monopoly power with respect to Bystolic. This illegal scheme enabled Forest to continue charging supra-competitive prices for Bystolic, without a substantial loss of sales, therefore reaping substantial, unlawful monopoly profits, all in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

254. Defendants and Hetero knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

255. Defendants and Hetero specifically intended that the pay-for-delay agreements would maintain Defendants' monopoly power in the relevant market, and thereby injure Plaintiff and Class Members.

256. Defendants and Hetero each committed at least one overt act in furtherance of the conspiracy.

257. As a direct, proximate, foreseeable, and intended result of Defendants' and Hetero's concerted monopolistic conduct, Defendants unlawfully maintained, enhanced, and extended its monopoly power, causing harm to Plaintiff and Class Members in the form of overcharge damages, as alleged herein. Specifically, without a reverse payment, Hetero would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Hetero would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Hetero side deal and other reverse payments.

COUNT 9 – VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDANTS AND TORRENT)

258. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

259. Defendants possessed, and will continue to possess, substantial market power (*i.e.*, monopoly power) in the relevant market at all times prior to September 17, 2021. Defendants possessed and will continue to possess the power to (1) prevent prices from falling in the relevant market; (2) exclude competitors from the relevant market; and (3) control and maintain the prices in the relevant market.

260. Through pay-for-delay deals, Forest and Torrent conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to delay and prevent market entry of generic Bystolic. Such agreements gave Forest 100% of Bystolic market sales in the United States until September 17, 2021; withheld the availability of generic versions of Bystolic to prevent any generic competition until September 17, 2021; and fixed and maintained the price Plaintiff and Class Members paid for Bystolic at supra-competitive levels.

261. The goal, purpose, and effect of Forest and Torrent's scheme was to maintain and extend Forest's monopoly power with respect to Bystolic. This illegal scheme enabled Forest to continue charging supra-competitive prices for Bystolic, without a substantial loss of sales, therefore reaping substantial unlawful monopoly profits, all in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

262. Defendants and Torrent knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

263. Defendants and Torrent specifically intended that the pay-for-delay agreements would maintain Defendants' monopoly power in the relevant market, and thereby injure Plaintiff and Class Members.

264. Defendants and Torrent each committed at least one overt act in furtherance of the conspiracy.

265. As a direct, proximate, foreseeable, and intended result of Defendants' and Torrent's concerted monopolistic conduct, Defendants unlawfully maintained, enhanced, and extended its monopoly power, causing harm to Plaintiff and Class Members in the form of overcharge damages, as alleged herein. Specifically, without a reverse payment, Torrent would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Torrent would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Torrent side deal and other reverse payments.

COUNT 10 – VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDANTS AND ALKEM)

266. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

267. Defendants possessed, and will continue to possess, substantial market power (*i.e.*, monopoly power) in the relevant market at all times prior to September 17, 2021. Defendants possessed and will continue to possess the power to (1) prevent prices from falling in the relevant market; (2) exclude competitors from the relevant market; and (3) control and maintain the prices in the relevant market.

268. Through pay-for-delay deals, Forest and Alkem conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to delay and prevent market entry of generic Bystolic. Such agreements gave Forest 100% of Bystolic market sales in the United States until September 17, 2021; withheld the availability of generic versions of Bystolic to prevent any generic competition until September 17, 2021; and fixed and maintained the price Plaintiff and Class Members paid for Bystolic at supra-competitive levels.

269. The goal, purpose, and effect of Forest and Alkem's scheme was to maintain and extend Forest's monopoly power with respect to Bystolic. This illegal scheme enabled Forest to continue charging supra-competitive prices for Bystolic, without a substantial loss of sales, therefore reaping substantial unlawful monopoly profits, all in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

270. Defendants and Alkem knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

271. Defendants and Alkem specifically intended that the pay-for-delay agreements would maintain Defendants' monopoly power in the relevant market, and thereby injure Plaintiff and Class Members.

272. Defendants and Alkem each committed at least one overt act in furtherance of the conspiracy.

273. As a direct, proximate, foreseeable, and intended result of Defendants' and Alkem's concerted monopolistic conduct, Defendants unlawfully maintained, enhanced, and extended its monopoly power, causing harm to Plaintiff and Class Members in the form of overcharge damages, as alleged herein. Specifically, without a reverse payment, Alkem would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent

settlement agreement whereby reasonable parties in the position of Forest and Alkem would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Alkem side deal and other reverse payments.

COUNT 11 – VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDANTS AND INDCHEMIE)

274. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

275. Defendants possessed, and will continue to possess, substantial market power (*i.e.*, monopoly power) in the relevant market at all times prior to September 17, 2021. Defendants possessed and will continue to possess the power to (1) prevent prices from falling in the relevant market; (2) exclude competitors from the relevant market; and (3) control and maintain the prices in the relevant market.

276. Through pay-for-delay deals, Forest and Indchemie conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to delay and prevent market entry of generic Bystolic. Such agreements gave Forest 100% of Bystolic market sales in the United States until September 17, 2021; withheld the availability of generic versions of Bystolic to prevent any generic competition until September 17, 2021; and fixed and maintained the price Plaintiff and Class Members paid for Bystolic at supra-competitive levels.

277. The goal, purpose, and effect of Forest and Indchemie's scheme was to maintain and extend Forest's monopoly power with respect to Bystolic. This illegal scheme enabled Forest to continue charging supra-competitive prices for Bystolic, without a substantial loss of sales, therefore reaping substantial unlawful monopoly profits all in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

278. Defendants and Indchemie knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

279. Defendants and Indchemie specifically intended that the pay-for-delay agreements would maintain Defendants' monopoly power in the relevant market, and thereby injure Plaintiff and Class Members.

280. Defendants and Indchemie each committed at least one overt act in furtherance of the conspiracy.

281. As a direct, proximate, foreseeable, and intended result of Defendants' and Indchemie's concerted monopolistic conduct, Defendants unlawfully maintained, enhanced, and extended its monopoly power, causing harm to Plaintiff and Class Members in the form of overcharge damages, as alleged herein. Specifically, without a reverse payment, Indchemie would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Indchemie would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Indchemie side deal and other reverse payments.

COUNT 12 – VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDANTS AND GLENMARK)

282. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

283. Defendants possessed, and will continue to possess, substantial market power (*i.e.*, monopoly power) in the relevant market at all times prior to September 17, 2021. Defendants possessed and will continue to possess the power to (1) prevent prices from falling in the relevant

market; (2) exclude competitors from the relevant market; and (3) control and maintain the prices in the relevant market.

284. Through pay-for-delay deals, Forest and Glenmark conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to delay and prevent market entry of generic Bystolic. Such agreements gave Forest 100% of Bystolic market sales in the United States until September 17, 2021; withheld the availability of generic versions of Bystolic to prevent any generic competition until September 17, 2021; and fixed and maintained the price Plaintiff and Class Members paid for Bystolic at supra-competitive levels.

285. The goal, purpose, and effect of Forest and Glenmark's scheme was to maintain and extend Forest's monopoly power with respect to Bystolic. This illegal scheme enabled Forest to continue charging supra-competitive prices for Bystolic, without a substantial loss of sales, therefore reaping substantial unlawful monopoly profits all in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

286. Defendants and Glenmark knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

287. Defendants and Glenmark specifically intended that the pay-for-delay agreements would maintain Defendants' monopoly power in the relevant market, and thereby injure Plaintiff and Class Members.

288. Defendants and Glenmark each committed at least one overt act in furtherance of the conspiracy.

289. As a direct, proximate, foreseeable, and intended result of Defendants' and Glenmark's concerted monopolistic conduct, Defendants unlawfully maintained, enhanced, and extended its monopoly power, causing harm to Plaintiff Class Members in the form of overcharge

damages, as alleged herein. Specifically, without a reverse payment, Glenmark would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Glenmark would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Glenmark side deal and other reverse payments.

COUNT 13 – VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDANTS AND AMERIGEN)

290. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

291. Defendants possessed, and will continue to possess, substantial market power (*i.e.*, monopoly power) in the relevant market at all times prior to September 17, 2021. Defendants possessed and will continue to possess the power to (1) prevent prices from falling in the relevant market; (2) exclude competitors from the relevant market; and (3) control and maintain the prices in the relevant market.

292. Through pay-for-delay deals, Forest and Amerigen conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to delay and prevent market entry of generic Bystolic. Such agreements gave Forest 100% of Bystolic market sales in the United States until September 17, 2021; withheld the availability of generic versions of Bystolic to prevent any generic competition until September 17, 2021; and fixed and maintained the price Plaintiff and Class Members paid for Bystolic at supra-competitive levels.

293. The goal, purpose, and effect of Forest and Amerigen's scheme was to maintain and extend Forest's monopoly power with respect to Bystolic. This illegal scheme enabled Forest to continue charging supra-competitive prices for Bystolic, without a substantial loss of sales,

therefore reaping substantial unlawful monopoly profits all in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

294. Defendants and Amerigen knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

295. Defendants and Amerigen specifically intended that the pay-for-delay agreements would maintain Defendants' monopoly power in the relevant market, and thereby injure Plaintiff and Class Members.

296. Defendants and Amerigen each committed at least one overt act in furtherance of the conspiracy.

297. As a direct, proximate, foreseeable, and intended result of Defendants' and Amerigen's concerted monopolistic conduct, Defendants unlawfully maintained, enhanced, and extended its monopoly power, causing harm to Plaintiff and Class Members in the form of overcharge damages, as alleged herein. Specifically, without a reverse payment, Amerigen would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Amerigen would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Amerigen side deal and other reverse payments.

COUNT 14 – VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE GENERIC AND BRANDED BYSTOLIC BETWEEN DEFENDANTS AND WATSON)

298. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

299. Defendant possessed, and will continue to possess, substantial market power (*i.e.*, monopoly power) in the relevant market at all times prior to September 17, 2021. Defendants

possessed and will continue to possess the power to (1) prevent prices from falling in the relevant market; (2) exclude competitors from the relevant market; and (3) control and maintain the prices in the relevant market.

300. Through pay-for-delay deals, Forest and Watson conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to delay and prevent market entry of generic Bystolic. Such agreements gave Forest 100% of Bystolic market sales in the United States until September 17, 2021; withheld the availability of generic versions of Bystolic to prevent any generic competition until September 17, 2021; and fixed and maintained the price Plaintiff and Class Members paid for Bystolic at supra-competitive levels.

301. The goal, purpose, and effect of Forest and Watson's scheme was to maintain and extend Forest's monopoly power with respect to Bystolic. This illegal scheme enabled Forest to continue charging supra-competitive prices for Bystolic, without a substantial loss of sales, therefore reaping substantial unlawful monopoly profits, all in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

302. Defendants and Watson knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

303. Defendants and Watson specifically intended that the pay-for-delay agreements would maintain Defendants' monopoly power in the relevant market, and thereby injure Plaintiff and Class Members.

304. Defendants and Watson each committed at least one overt act in furtherance of the conspiracy.

305. As a direct, proximate, foreseeable, and intended result of Defendants' and Watson's concerted monopolistic conduct, Defendants unlawfully maintained, enhanced, and

extended its monopoly power, causing harm to Plaintiff and Class Members in the form of overcharge damages, as alleged herein. Specifically, without a reverse payment, Watson would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Watson would have agreed upon earlier entry dates, untainted by delay associated with the unlawful Watson side deal and other reverse payments.

COUNT 15 – VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (MONOPLIZATION AND MONOPOLISTIC SCHEME – FOREST/ALLERGAN/ABBVIE)

306. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

307. Defendants possessed, and will continue to possess, substantial market power (*i.e.*, monopoly power) in the relevant market at all relevant times prior to September 17, 2021. Defendants possessed and will continue to possess the power to (1) control prices in the relevant market, (2) prevent prices from falling in the relevant market, and (3) exclude competitors from the relevant market.

308. By entering into the reverse-payment agreements with the Generic Competitors, Defendants willfully and intentionally maintained, enhanced, and extended their monopoly power using restrictive or exclusionary conduct, rather than by means of greater business acumen, and thereby injured Plaintiffs and Class Members. Specifically, Defendants (a) allocated to themselves 100% of Bystolic market sales in the United States until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supra-competitive levels, the price Plaintiff and Class Members paid for Bystolic.

309. It was Defendants' conscious objective to further their dominance in the relevant market by and through the anticompetitive conduct alleged herein.

310. Defendants' anticompetitive conduct harmed competition as alleged herein.

311. As a direct, proximate, foreseeable, and intended result of their illegal and monopolistic conduct, Defendants unlawfully maintained, enhanced, and extended their monopoly power, and Plaintiff and Class Members were harmed as a result, as alleged herein.

312. All of Forest's corporate successors adopted Defendants' monopolistic scheme and took actions in furtherance thereof.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Members of the Direct Purchaser Class pray for relief as set forth below:

1. Certification of the Direct Purchaser Class pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiff as Class Representative for the Direct Purchaser Class;

2. Permanent injunctive relief that enjoins Defendants from violating the antitrust laws and requires it to take affirmative steps to dissipate the effects of the violations;

3. An adjudication and decree that the acts alleged herein constitute an unlawful conspiracy to monopolize in violation of the Sherman Act, 15 U.S.C. § 1;

4. An adjudication and decree that the acts alleged herein constitute an unlawful monopolization in violation of the Sherman Act, 15 U.S.C. § 2;

5. The entry of joint and several judgments against Defendants for the damages sustained by Plaintiff and the Direct Purchaser Class defined herein and for any additional damages, penalties, and monetary relief provided by applicable law, including treble damages;

6. An award to Plaintiff and Members of the Direct Purchaser Class pre-judgment and post-judgment interest as provided by law, at the highest legal rate from and after the date of service of the complaint in this action;

7. An award of the costs of this suit, including reasonable attorneys' fees; and

8. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, on behalf of itself and others similarly situated, pursuant to Federal Rule of Civil Procedure 38, hereby requests a jury trial on any and all claims so triable.

DATED: October 20, 2020

Respectfully submitted,

/s/ Dianne M. Nast
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